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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,782	04/12/2001	D. Wade Walke	LEX-0161-USA	1934
24231	7590	07/03/2002		
LEXICON GENETICS INCORPORATED 8800 TECHNOLOGY FOREST PLACE THE WOODLANDS, TX 77381-1160			EXAMINER	
			WALICKA, MALGORZATA A	
ART UNIT	PAPER NUMBER			
1652	10			
DATE MAILED: 07/03/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/833,782	WALKE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Malgorzata A. Walicka	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 April 2002.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____                                    |

Amendment and Response to Office Action filed April 23, 2002 as paper 8 is acknowledged. The amendments to the claims have been entered as requested. Claims 1 and 3 are amended. Claims 1-3 are pending in the application and are the subject of this Office Action.

### **Detailed Action**

#### **1. Objections**

##### *1.1. Specification*

Objection to claim 3 is withdrawn in the light of Applicants amendments.

#### **2. Rejections**

##### *2.1. 35 USC section 101*

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention lacks specific and substantial utility for the reasons set forth in the prior Office Action, Paper No. 8. Claims 1-3 are rejected under 35 USC section 112, first paragraph for the same reasons.

Applicants argue that utility of DNA molecules of SEQ ID NO: 1 is supported by GENBANK Accession No. AJ300837 (Exhibit C) describing a sequence that encodes a neutrolysin. According to Applicants said sequence is in 99% identical to sequence SEQ ID NO: 1 of the instant application: "(2113 of a total of 2115 bases presented in SEQ ID NO: 1)." The GENEBANK sequence is 2890 nucleotides long, and therefore, cannot be 99% identical to SEQ ID NO: 1 that is 2115 nucleotides long. Even if the

coding regions of both sequences are different only in three nucleotide positions that does not mean that the polypeptide encoded by SEQ ID NO: 1 has the same activity as that encoded by GENBANK Accession No. AJ30083. Those skilled in the art realize that neutrolysins are highly specific proteases and a change of a single nucleotide in the coding region may change the specificity of the encoded protein or render it inactive. Thus, Applicants' argument has been fully considered but is found not persuasive.

In addition, Applicants direct the examiner's attention to the use of the claimed sequence in a gene chip format, which is a prove of its substantial, "real world" use, because "there is an entire industry established on the use of a gene sequences or fragments thereof in a gene chip format."

The gene chip format, as indicated by its name and stressed by Applicants, may be use for small fragments of gene, that is for DNA molecules that do not encode any protein having a biological function. Any DNA molecule, even the one that has no specific and substantial utility can be used in the gene chip assay. Thus, the possibility of usage of DNA molecules of SEQ ID NO: 1 in the gene chip format assay is not a proof that the molecule has a specific and substantial utility.

Furthermore, Applicants assert: "Yet another example of the utility of the present invention is in expanding the utility of data coming from the human genome project." This argument is not persuasive, because expanding the utility of data coming from the human genome project is not considered a specific and substantial utility.

*2 .2. 35 USC section 112, second paragraph*

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the amendment introducing the word "highly" before the word "stringent" does not explicitly enter specific hybridization conditions given on page 4, lines 14. Specifying the hybridization conditions in the claim will obviate this rejection.

#### *2.3. 35 USC section 112, first paragraph*

Rejection of claim 1 made in the previous Office Action under 35 U.S.C. 112, first paragraph, for lack of written description and scope of enablement is withdrawn because the claim has been amended.

#### *2.4. 35 USC section 102*

Rejection of claim 1 as being anticipated by Kato A. et al is withdrawn because the claim has been amended.

### **3. New rejection**

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim 2, part a) is rejected because it does not indicate the function of the isolated nucleic acid molecule and the specification characterizes this DNA molecule by the function of encoding the polypeptide of SEQ ID NO: 2 that has no specific function.

As concerns part (b) of the claim, the hybridization process leads to the isolation of a large genus of the DNA molecules. The specification discloses only a single species of the claimed genus, i.e.,SEQ ID NO: 1 and fails to describe additional representative species of these DNA. Also the application fails to identify any function characteristics of any nucleic acid of any kind. There is no disclosure of any particular structure to function/activity relationship even in the single disclosed species, i.e. SEQ ID NO: 1. Thus, predictability of the function of the representatives of the claimed genus is not apparent. Given the lack of characteristics of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Even if the utility of SEQ ID NO: 2 has been taught by Applicants, the following rejection would apply. *wrong*

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the DNA identified by SEQ ID NO: 1, does not reasonably provide enablement for all the DNA molecules that comprise a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The genus of DNA molecules selected by the hybridization process is a large variable genus encompassing the species that do not encode a protein having the desired

functionality. Thus, the scope of the claim covers DNA molecules that are not enabled in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meliorate A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Patent Examiner

  
NASHAAT T. NASHED PH.D.  
PRIMARY EXAMINER